

Appl. No. : 10/687,523  
Filed : October 15, 2003

### REMARKS

Claims 1-11, and 18-26 have been canceled without prejudice. Applicant reserves the right to pursue the subject matter of the cancelled claims in a related application. Claim 12 have been amended. Support for the amendments can be found in the Specification as filed in paragraphs [0011], [0043-[0044] and Example 4. Therefore, no new matter has been introduced by these amendments.

#### Definiteness

The Examiner has maintained the rejection of Claims 12-17 under 35 USC §112, second paragraph as being allegedly indefinite. More specifically, Claim 12 was found indefinite for not reciting a reference to SEQ ID NO: for amino acid position 481. The Examiner has requested the sequence be brought into the Specification, and the Claims amended to recite the sequence identifier. Applicants maintain that because the sequence of ClCk<sub>B</sub> had been published in GenBank under accession number NM\_000085, as described in the Specification, the position 481 recited in Claim 12 is definite. However, to expedite the allowance of this application, Applicant has now amended the Specification and Claim 12 as requested by introducing the sequence identifiers of the ClCk<sub>B</sub> of polynucleotide and polypeptide sequences.

Additionally, the Examiner has found Claim 12 as indefinite for being unclear as to what activity is being modulated and suggested amending the claim to recite “modulating reabsorption of sodium chloride”. Applicant has now amended Claim 12 to recite “modulating reabsorption of sodium chloride or Cl<sup>-</sup> transport...” Support for the amendments can be found in the Specification as filed in paragraphs [0011], [0043-[0044] and Example 4. Because the specification clearly supports not only a method for identifying substances that modulate the reabsorption of sodium chloride by a mutated ClCk<sub>b</sub> protein, but also substances that modulate Cl<sup>-</sup> transport by said protein (see e.g., Example 4), Applicant has modified the Examiner’s proposed amendment to include the addition of Cl<sup>-</sup> transport. In Example 4, the mutated ClCk<sub>b</sub> protein was expressed in defolliculated oocytes. The oocytes were incubated with reaction buffer which contained several chloride salts (NaCl, KCl, CaCl<sub>2</sub>, and MgCl<sub>2</sub>), which when brought into an aqueous environment, dissociate into Cl<sup>-</sup> and the corresponding complex partner. Subsequently, voltage pulses were applied to the stored oocytes and the current, constituted by the

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Cl<sup>-</sup> ions flowing across the oocyte membranes, was measured. Thus, the disclosed method measures transport of dissociated Cl<sup>-</sup> ions by the mutated ClCkb protein.

The Examiner further maintained that Claim 12 is unclear in reciting “polypeptide”, while Claim 15-17 lack the antecedent basis in claim 12 because a 100 amino acid peptide would not be able to form a pore for a chloride channel. Applicant maintains that the definition of polypeptide coupled with its function as capable of modulating reabsorption or transport of sodium chloride or Cl<sup>-</sup> makes Claim 12 clear. However, to expedite the allowance of the present application, Claim 12 is now amended to recite chloride channel Kb protein.

In view of these amendments, Claims 12-17 are now definite and their rejection under 35 USC §112, second paragraph should be withdrawn.

The Examiner has maintained the rejection of Claims 12-17 under 35 USC §112, first paragraph as allegedly lacking written description. More specifically, the Examiner maintains that there is no written description regarding how to measure ion conductance across membranes comprising a peptide of less than 100 amino acids derived from ClCkb and comprising the T481S mutation. Applicant disagrees for the reasons of record. However, to expedite the allowance of the present application, Claim 12 is now amended as in accordance with the Examiner’s suggestion to recite ClCkb protein. Therefore, currently amended Claims 12-17 are supported by the Specification and their rejection under 35 USC §112, first paragraph should be withdrawn.

### CONCLUSION

Applicants have endeavored to address all of the Examiner’s concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of all of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.


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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By:   
Mark R. Benedict  
Registration No. 44,531  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

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